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June 7, 1999

Dockets Management Branch
Food and Drug Administration
Department of Health and Human Services
12420 Parklawn Drive Room I-23
Rockville, MD 20857

RE: Citizen's Petition: Request for an Exemption

Enclosed please find a Request for an Exemption from the Performance Standard of 21 CFR Part 898, Performance Standard for Electrode Lead Wires and Patient Cables. This petition includes a sample device, to facilitate understanding of the rationale behind this exemption petition, as well as device labeling.

Should there be any questions, or further information we can provide to help in your analysis, please do not hesitate to contact the undersigned.

Sincerely,
MEDTRONIC, INC.

Susan Noddin

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Product Regulation Manager
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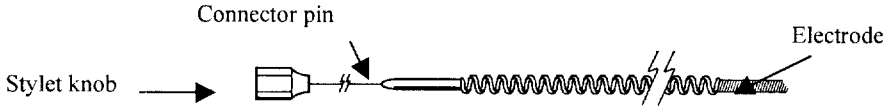
CITIZEN PETITION

REQUEST FOR AN EXEMPTION

The undersigned submits this petition under 21 CFR §898.14 to request the Commissioner of Food and Drugs ("CFD") to exempt the devices described below from the Performance Standard of 21 CFR Part 898 Performance Standard for Electrode Lead wires and Patient Cables.

Description of Products

This petition relates to devices generally known as temporary test stimulation leads, which are classified as Class III devices under 21 CFR 870.3680. A diagram of a test stimulation lead is shown below (not to scale). Also enclosed with this submission is a sample test stimulation lead and foramen needle, to allow a sense of scale of the devices.

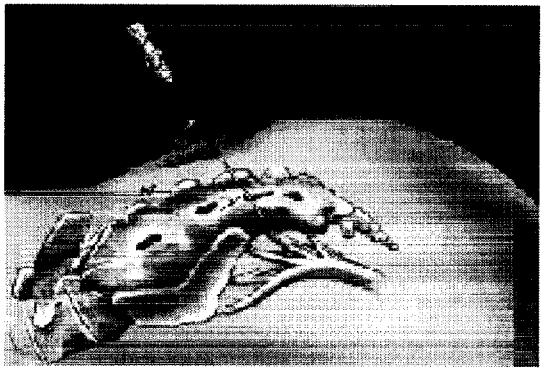


Labeling, in the form of instructions for use for the Medtronic InterStim Model 3057 Temporary Test Stimulation Lead, is attached as Exhibit A.

Use of a Test Stimulation Lead

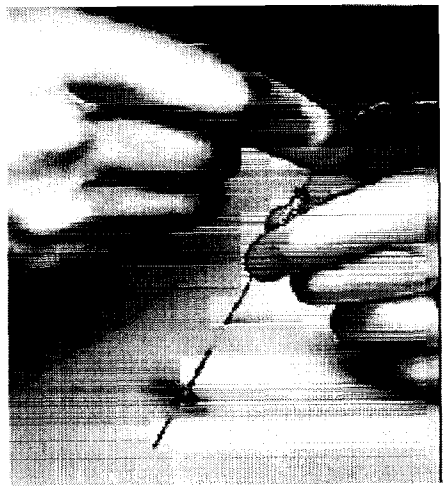
The Medtronic InterStim temporary test stimulation lead is used to screen potential patients for chronic (implanted) sacral nerve stimulation therapy for control of urinary voiding dysfunctions, including urge incontinence, urgency/frequency, and retention. The test stimulation evaluates whether a patient has appropriate response to stimulation of the sacral nerves, and a resultant improvement in voiding symptomologies. The method of use is as follows:

a) A patient is placed face-down on an examination table, with flexure at the waist to allow the clinician a good view of the sacrum and perineum. (Note that this positioning of the patient means that the patient does not view any of the procedure, does not see the connector that is the subject of this petition, and is unlikely to be aware of its existence.) The clinician inserts a 20-gauge foramen needle, with an inside diameter of 0.0255", into the S3 foramen.

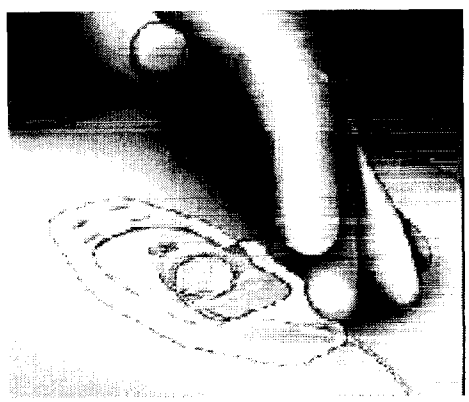


The shaft of the needle is electrically insulated, except for the most proximal and most distal

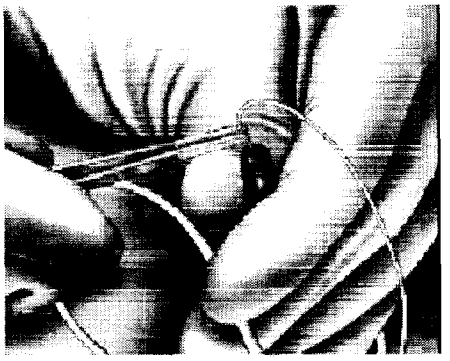
ends. Stimulation is applied at the proximal end, and the patient is observed for appropriate physiological responses (flexure of big toe, "bellows" contraction in perineal area). When the needle is positioned where the best response is obtained, the test stimulation lead is threaded through the lumen of the foramen needle, until the electrode is exposed at the tip, inside the sacral foramen.



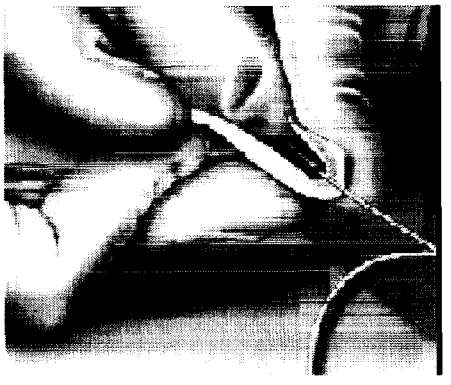
Acute stimulation is repeated, to ensure correct placement. When placement is determined to be optimal, the stimulation source is disconnected, the lead stylet is removed, and the foramen needle is threaded back off the proximal portion of the stimulation lead. The lead is then taped in place; excess length is coiled and taped with Tagaderm over the exit site.



The lead electrode is inserted into the female connector of a screener cable, which plugs into an external, portable test stimulator.



The lead electrode / cable connector juncture is wrapped with tape by the clinician, minimizing the potential for disconnection while the patient is at home.



The patient goes home for 3-7 days, wearing the test stimulator at the beltline.
At the end of a week, the clinician removes the test stimulation lead and discards it.

Reasons Why Compliance with the Performance Standard is Infeasible

In order to meet the performance standard, one must meet subclause 56.3(c) of the international standard IEC60601-1. This requires that the connector meet three test requirements: (1) the conductive elements must not make contact with the live parts of a mains socket, (2) the standard test finger must not make contact with the conductive elements of the connector, and (3) the conductive elements of the connector must not be able to touch a flat conductive surface. Obviously, a 0.6 mm connector pin cannot meet any of these tests.

The original rationale behind this performance standard was a patient cable designed with a pin that appeared appropriate for insertion into a mains outlet, which subsequently was (inappropriately) connected into a mains outlet, causing patient injury. The lead that is the subject of this petition is so thin, and the connector so small, that it could not be mistaken to be an intended mains connector, either by a clinician nor a patient. Further, this connector is small that in the extremely unlikely case that someone were to attempt to insert this into a mains connection, the connector would fall out of the outlet.

The entire purpose of the thin diameter of the wire and the connector is so that it may pass through a 20-gauge foramen needle, and that the needle may be removed by sliding over the connector end of the lead. The only connectors that pass the standard are very large in relation to a 20-gauge foramen needle, and indeed, the needle would not be able to pass over the end of a lead which features insulated connectors of this type.

The use of a larger-bore foramen needle would be infeasible for several reasons: A larger bore needle would increase the risk of sacral nerve damage when inserting the needle. Moreover, a larger "puncture wound" at the entrance site increases patient discomfort and the potential for infection. Bowel perforation (which could happen if the foramen needle is inserted too deeply) is rarely seen, however, the small bore of the current foramen needle ensures that the tissues will "self-seal" if the bowel is inadvertently perforated. A puncture with a larger bore needle will be less likely to "self-seal," increasing the risk of peritonitis. Finally, the maximum diameter of the needle as a lead introducer is limited by the diameters of the sacral foramen themselves; most safety connectors which pass the standard are larger than the diameter of the typical sacral foramen.

Therefore, the medical consequences of complying with the performance standard results in risks far greater than the exceedingly unlikely risk of electrical shock associated with the existing design.

Reasons That Mitigate The Risk.

Risk is minimized by nature of the environment and usage of this device. Device implant is only performed by medical professionals, well-trained in the correct usage of this device. The length of lead exiting the implant site is coiled and bandaged in place against the skin by the implanting physician; the exposed pin is physically close to the patient and does not extend beyond the patient environment. The positioning of the patient during the procedure minimizes their view of the device being implanted.

The patient is not expected as a part of this therapy to reconnect any part of the system once they are home; indeed, if the screener cable – test stimulation lead disconnected, it would be very difficult for the patient to reach back and reconnect this on their own. The patient is sent home with connecting cable attached to the test stimulator and test stimulation lead, and detailed instructions regarding proper use of the device, precautions to take (no bathing, etc.) during the test period. Patients receive a "Patient Manual" which explains in detail the "Do's and Don'ts" of the therapy.

After three to seven days, the patient returns to the clinical setting. The test stimulator is turned "OFF," and the lead is disconnected from the test stimulator by the clinician. The bandages and tape are removed, and the test stimulation lead is removed by gentle traction. The lead is then discarded. The fact that health care professionals are performing this procedure greatly reduces the risk of insertion in an AC mains outlet or inappropriate medical equipment.

The technical manuals warn against contact with exposed metal surfaces. "Connect the test stimulation lead only to the Model 3625 Test Stimulator. Avoid unintentional contact between the lead and any equipment used or any conductive surface in contact with the equipment."

Test stimulation leads have been implanted commerically for five years. There have been no reports of patient injury related to exposed pins to date with any lead design introduced through a foramen needle.

Scope of Petition

Test stimulation leads have been in use for 5 years without any reported instance of patient injury due to improper insertion of the pin connector. Therefore, applicant seeks an exemption for all test stimulation leads, rather than providing a specific model number requiring the agency to go through an exemption for successive test stimulation leads. Medtronic seeks exemption for all Medtronic test stimulation leads which are introduced through the lumen of a foramen needle.

Environmental Impact

There is no environmental impact statement needed because this Petition, as an exemption from a standard, is automatically exempt under 21 CFR §25.24(e)(3).

Certification

The undersigned certifies that, to the best knowledge of the undersigned, this petition includes all information and views on which the Petitioner relies and includes representative that information known to Petitioner which are unfavorable to the petition.

Yours truly,

Susan Noddin

Susan Noddin
Product Regulation Manager
Medtronic, Inc.

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